

## REMARKS

Reconsideration of the application is respectfully requested.

### **I. Status of the Claims**

Claims 1 – 3, 8 and 9 are presently pending, with claims 4 – 7 having previously been canceled without prejudice or disclaimer and claim 9 having previously been withdrawn from consideration due to restriction. Applicants amend claim 1. No new matter is introduced. Support for the amendments may be found, for example, with reference to Applicants' specification at page 11, line 20 through page 13, line 16.

### **II. Rejection under 35 U.S.C. § 103**

Claims 1-3 and 8 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,554,789 to Brugger et al. ("Brugger"). Applicants amend claim 1 to further clarify the nature of their invention, and respectfully traverse the rejections of claims 1-3 and 8 under 35 U.S.C. § 103(a).

In amended independent claim 1, Applicants claim:

**1. A blood purification device comprising:**

a blood circuit having an arterial blood circuit and a venous blood circuit;

a blood pump disposed in said arterial blood circuit, the blood pump being operable to provide a preset blood flow rate  $Q_b$ ;

a blood purifier connected to the blood circuit between said arterial blood circuit and said venous blood circuit, and configured to purify blood flowing in said blood circuit, the blood purifier being operable to provide a preset water removal rate  $Q_{uf}$ ;

a first measuring unit disposed in said arterial blood circuit wherein said first measuring unit measures a first hematocrit value  $H_{ta}$  of said arterial blood circuit;

a second measuring unit disposed in said venous blood circuit wherein said second measuring unit measures a second hematocrit value Htv of said venous blood circuit;

a calculating unit configured to calculate a measured ratio value and a theoretical ratio value, and then to calculate an evaluation value comparing a closeness of the measured ratio value to the theoretical ratio value, wherein:

the first measured hematocrit value Hta is divided by the second measured hematocrit value Htv to obtain the measured ratio value Hta/Htv, and

the preset water removal rate Quf is divided by the preset blood flow rate Qb to obtain the theoretical ratio value  $1 - Quf/Qb$ ;

an evaluation unit coupled to the calculating unit and configured to evaluate whether the evaluation value is larger than a predetermined value; and

a reporting unit configured to report a trouble condition indicating a malfunction for at least one of said blood pump and said blood purifier when the evaluation value, based on the first measured hematocrit value Hta and the second measured hematocrit value Htv, is larger than the predetermined value.

(Emphasis added).

Brugger discloses a layered fluid circuit for use, for example, in a hemofiltration (dialysis) machine (*see, e.g.,* FIG. 11 of Brugger). The machine disclosed by Brugger includes arterial and venous blood circuits, a blood pump, a blood purifier (dialyzer), and sensors disposed in each of the arterial and venous blood circuits for measuring hematocrit values. Brugger also discloses an ultrafiltration pump provided in the dialyzer which may be controlled to facilitate the removal of waste fluids at a prescribed waste fluid flow rate, and Brugger discloses that the blood pump may be controlled to provide a prescribed blood flow rate. As acknowledged by the Examiner, Brugger does not explicitly disclose Applicants' claimed calculation unit that calculates a measured ratio value  $Hta/Htv$ , a theoretical ratio value  $1 - Quf/Qb$ , and an evaluation value comparing the closeness of the measured ratio value to the theoretical ratio value. The Examiner also acknowledges that Brugger does not explicitly disclose Applicants' claimed evaluation unit that evaluates whether the evaluation value is larger than a predetermined value, or Applicants' claimed reporting unit that reports a trouble condition when the evaluation value is large than the

predetermined value. However, the Examiner never-the-less finds claim 1 to be obvious in view of Brugger according to the following arguments:

[1] Applicant's specification does not disclose that the evaluation unit evaluating whether the evaluation value is larger than a first predetermined acceptable ratio difference serves any stated purpose or solves any particular problem as compared to the prior art. ... [2] Applicant has not disclosed that the process of comparing ratios produces any differences from the prior art in the device's output to the patient. ... [3] Given that Brugger teaches all of the structural limitations of the claims, including a pair of measuring units measuring pre-treatment hematocrit and post-treatment hematocrit in the arterial and venous blood circuits, as well as detecting leaks and other trouble conditions, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Brugger to use a suitable mathematical formula to calculate when the theoretical values differ enough from the measured values to determine that a trouble condition exists.

Applicants respectfully disagree with the Examiner's first and second arguments. Applicants' claimed evaluation unit, in combination with Applicants' claimed calculating and reporting units, serve the purpose of providing a mechanism for monitoring the operation of the blood pump and the blood purifier "on-line" during the operation of the blood purification device (*see*, e.g., page 13, lines 11 – 21 of Applicants' specification). While the device of Brugger includes leak sensors that may detect associated air or blood leakage during the operation of Brugger's device, Brugger's device relies on "off-line" testing prior to operation of the device in order to determine the that the blood pump and the blood purifier pumps are operable (*see*, e.g., Col. 24: 36 – 43 of Brugger). As a result of detecting an associated pump trouble during the operation of the blood purification device, Applicants' claimed device causes the device to be halted (*see*, e.g., page 13, lines 18 – 21 of Applicants' specification). Thus, Applicants claimed device solves the problem not addressed in the prior art of directly detecting a malfunction of the blood pump and blood purifier during the operation of the blood purification device, reporting an associated trouble condition to the patient and enabling the device to be shut down. In contrast to the prior art, Applicants' claimed device provides the patient with a trouble report that specifically diagnoses a failure of one of the blood pump or blood purifier during the operation of the device.

Applicants also respectfully disagree with the Examiner's third argument. Applicants submit a Declaration under 37 C.F.R. § 1.132 made by one of the inventors, Mr. Yoshihiro Mori. As is evident from the description of Mr. Mori's experience and qualifications in this Declaration, Applicants submit that Mr. Mori has direct knowledge of the level of ordinary skill at the time of the present invention for blood purification devices. In the Declaration, Mr. Mori describes the prior art (including Brugger), and explains in his opinion why one of skill in the prior art at the time of the present invention would have been skeptical as to the effectiveness of the calculating and evaluating functions of Applicants' claimed device. Mr. Mori also describes the significant benefits gained from applying the claimed invention, in particular, to blood purification devices directed to the home dialysis market. In view of this evidence, Applicants respectfully submit that one of skill in the prior art would not have found it obvious to modify Brugger at the time of the present invention to perform the calculating and evaluating functions of Applicants' claimed device as claimed in amended independent claim 1

For at least the above-argued reasons, Applicants submit that amended independent claim 1 is not obvious in view of Brugger and stands in condition for allowance. As claims 2, 3 and 8 depend from allowable independent claim 1, Applicants further submit that dependent claims 2, 3 and 8 are also allowable for at least this reason.

Accordingly, Applicants respectfully request that rejections of claims 1-3 and 8 under 35 U.S.C. § 103(a) be withdrawn.

**CONCLUSION**

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance. If there are any remaining issues which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

By  \_\_\_\_\_

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